NAIMA
NORTH AMERICAN INSULATION
MANUFACTURERS ASSOCIATION

VIA E-MAIL AND OVERNIGHT MAIL

May 6, 2010

Ruth M. Lunn, Ph.D.
Director, Report on Carcinogens Group
National Toxicology Program
National Institute of Environmental Health Sciences
KEY615 – Keystone Park, 2006, MD KY-14
615 Davis Drive
Durham, NC 27713

RE: Draft Substance Profile – Glass Wool Fibers

Dear Dr. Lunn:

The North American Insulation Manufacturers Association ("NAIMA") and its members are surprised and deeply disappointed that the National Toxicology Program ("NTP") staff preparing the draft Substance Profile has not followed the Glass Wool Expert Panel's unanimous recommendation to delist glass wool. This is particularly troubling given that the Expert Panel's classification recommendation was consistent with the 2002 International Agency for Research on Cancer ("IARC") decision to delist glass wool fibers, while retaining special purpose fibers of concern as a possible carcinogen.

The draft Substance Profile creates a deep concern for the insulation glass wool fiber industry in the United States because these very same glass fibers that were delisted by IARC and recommended for delisting by the Expert Panel are not classified as carcinogens or subject to labeling requirements in any other jurisdiction in the world. Therefore, this inconsistency with IARC and the Expert Panel misses the opportunity for a globally harmonized treatment of these fibers.

The draft Substance Profile specifically recognizes that most of the fibers within the category of "Glass Wool Fibers (Respirable) as a Class" are not "reasonably anticipated to be a human carcinogen." The draft Substance Profile specifically states:

- At page 1 – "Carcinogenicity within the class of respirable glass wool fibers varies, and not all fibers within this class cause cancer."
- At page 1 – "Thus the carcinogenicity of individual glass wool fibers must be evaluated on a case-by-case basis. . ."

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- At page 1 – "The European Community and Germany have standardized *in vivo* testing of fibers for carcinogenicity and issued criteria for classifying the carcinogenicity of synthetic vitreous fibers. . ."
- At page 2 – "The majority of studies that found carcinogenic effects of glass wool fibers tested special-purpose fibers."
- At page 9 – "The European Union and Germany have established criteria for labeling and classifying synthetic vitreous fibers (including glass fibers) based on their potential to be hazardous to human health, which is dependent both on a fiber's physical dimensions and its chemical composition. . ."
- At page 9 – "Special-purpose glass fibers are limited-production materials (~1% of total production) compared with insulation glass wool. . ."
- At page 10 – "Special-purpose glass fibers make up a very small percentage of the total synthetic vitreous fibers produced in the United States, accounting for only about 1% of the total annual production."
- At page 1 – "Studies in experimental animals demonstrated a greater carcinogenic effect for special-purpose fibers. . . than for the respirable fraction of glass fibers typically used as insulation wools."

NAIMA supports the draft Substance Profile's recognition of the existence of fibers within the proposed classification of fibers that are not "reasonably anticipated to be a human carcinogen" and its ratification of the European Union's approach for identifying and acknowledging such fibers.

Specifically, the European Union (Note Q of the Regulation (CE) n°1272/2008) has a system to exonerate from classification as carcinogens and labeling requirements the very fibers that were recommended for delisting by the Expert Panel. Australia and New Zealand have also adopted this same European Standard. Exoneration is based on compliance with the very detailed EU Regulation criteria based on tests done according to EU guideline ECB/TM27 rev. 7:

- A short-term biopersistence test by inhalation has shown that the fibers longer than 20 µm have a weighted half-life less than 10 days; or
- A short-term biopersistence test by intratracheal instillation has shown that the fibers longer than 20 µm have a weighted half-life less than 40 days; or
- An appropriate intra-peritoneal test has shown no evidence of excess carcinogenicity; or
- Absence of relevant pathogenicity and neoplastic changes in a suitable long-term inhalation test.

The EU Official Journals that contain the Regulations (CE) n°1272/2008, including the exoneration criteria of Note Q and the Regulations (CE) N°790/2009 amending it, can be found respectively at:

- http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:353:0001:1355:en:PDF
- http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:235:0001:0439:en:PDF

NAIMA's member companies already produce many glass wool products in the United States and Europe that are exonerated under the Note Q EU Regulation. Those products are not required to carry a cancer label in Europe or Canada but are currently required to be labeled in the United States. Continuation of the status quo is inequitable and scientifically unjustifiable, especially in light of the many accurate statements contained in the draft Substance Profile and noted above.

To address this issue, NAIMA respectfully requests that NTP revise the draft Substance Profile to make clear that those fibers that have been shown in valid animal studies to have no carcinogenic hazard are not considered by NTP as "reasonably anticipated to be a carcinogen." NAIMA specifically suggests that the first full paragraph under the "Carcinogenicity" heading on the first page of the draft Substance Profile read as follows:

> Carcinogenicity within the class of respirable glass wool fiber varies, and not all fibers within this class cause cancer. Thus, those fibers exonerated under the EU *in vivo* testing standards would not be reasonably anticipated to be a human carcinogen.

A similar conforming change to page 9 would read as follows:

> Carcinogenicity within the class of respirable glass wool fibers varies, and not all fibers within this class cause cancer. Thus, those fibers exonerated under the EU *in vivo* testing standards are not considered to have "reasonably anticipated" status in the *Report on Carcinogens*.

These two changes would both harmonize the Substance Profile with all other hazard classification determinations worldwide and further promote the NTP's goal of providing incentives to manufacturers to move to ever more soluble and less hazardous fibers.

NAIMA will be submitting more detailed comments by the June 7, 2010 deadline. We submit these comments now because of the urgency of the issue and the need to promote more meaningful public comments on the revised draft Substance Profile and to the Board of Scientific Counselors. We also note that the draft Substance Profile has already been modified once since its first publication. The Federal Register notice provides that "Although the deadline for submission of written comments to be considered at the BSC meeting is June 7, 2010 (*see* "Request for Comments" above), the NTP welcomes comments or additional information on these study nominations at any time."

These important additions would rectify the inconsistency in the international scientific community that would result from adoption of the current version of the draft Substance Profile.

Sincerely,

Angus E. Crane

Angus E. Crane
Executive Vice President, General Counsel

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